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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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09/518,076

03/03/2000

Leland Shapiro

SHAP-000200

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09/03/2008

Don D. Cha

547 Buena Vista Road

Golden, CO 80401

EXAMINER

HILL, MYRON G

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

09/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|----------------------------------------|--|
| Office Action Summary | Application No. 09/518,076 | Applicant(s) SHAPIRO, LELAND | |
| | Examiner MYRON G. HILL | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-12, 16, 28, 31 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) 10, 11, 16, 28, 31 and 38-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12-14 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to the response and petition filed 6/9/08 and follows the petition decision of 6/20/08 at which time the application was forwarded to the examiner.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/9/08 has been entered.

Claim 41 is newly added.

Claims 1-8, 12 and 41 are under consideration.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 recites the limitation "substance" in line 1. There is insufficient antecedent basis for this limitation in the claim.

The claim has been canceled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1- 8, and 12 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lezdey (US 5,532,215,) and Guittard *et al.* (US 5358721).

Applicant has amended the claims and the rejection is withdrawn.

Rejection Necessitated By Amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5-8, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Lezdey (US 5,532,215, previously cited and discussed in prior actions).

The claims are drawn to treating a subject suffering from a disease associated with a herpes virus infection by administering a peptide with AAT activity. Applicant has amended the claims to limit the treatment to a subject suffering a disease associated with herpes infection and to remove the combination treatment limitation.

Lezdey teaches AAT topical formulas to treat virally induced rashes and lesions as well as other inflammatory dermatological conditions associated with disease (Example 1, column 7). The conditions treated in this example (rashes and lesions as well as other inflammatory dermatological conditions) are the same as the general term of atopic eczema.

Thus, Lezdey anticipates the claimed invention.

Claim Rejections - 35 USC § 103

Claims 1, 3, 4 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lezdey (US 5,532,215).

Claim 1 is discussed above and the dependent claims add a list of conditions. Claim 41 requires preventing an outbreak of a disease associated with herpes virus infection

Applicant argues that the claims have been amended to a method to treat a disease associated with herpes infection, not a method to kill or inhibit replication of herpes.

Applicant's arguments have been fully considered and not found persuasive.

The amended claims do not exclude treating the herpes infection to treat associated diseases or preventing the outbreak of associated diseases.

Lezdey teaches that AAT treatment can be used against HIV and viruses associated with other conditions (column 6, lines 25-36) as well as other inflammatory dermatological conditions associated with disease (Example 1, column 7).

One of ordinary skill in the art at the time of invention would have known that treating herpes infection would also reduce diseases associated with herpes infection and that treating the herpes would prevent the outbreak of herpes associated diseases because the underlying cause, herpes virus infection, is treated.

Thus, it would have been *prima facie* obvious to treat herpes associated diseases by treating herpes as taught by Lezdey with the expectation of success because Lezdey teaches how to treat herpes and associated conditions with AAT peptides.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MYRON G. HILL whose telephone number is (571)272-0901. The examiner can normally be reached on 5:30 am-2 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/M. G. H./

Examiner, Art Unit 1648

/Bruce Campell/

Supervisory Patent Examiner, Art Unit 1648

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| <div><i>Application Number</i></div> <div></div> | Application/Control No. | Applicant(s)/Patent under Reexamination | |
| | 09/518,076 | SHAPIRO, LELAND | |
| | Examiner | Art Unit | |
| | MYRON G. HILL | 1648 | |
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